

NO. 4:11-CR-1. ERIN

Plaintiff,

MARC S. HERMELIN,

INFORMATION

1. At all times relevant to this Information, Defendant Marc S. Hermelin (“Hermelin”) was a resident of St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri. Defendant is a citizen of both the United States and Israel.
2. During all times relevant to this Information, defendant Hermelin was associated with KV Pharmaceutical (“KV”). KV, through several subsidiary corporations including Ethex Corporation (“Ethex”), operated manufacturing facilities and maintained corporate offices in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri. KV and defendant developed, manufactured, promoted, sold, and distributed into interstate commerce assorted tablet drugs intended for human consumption.
3. Defendant Hermelin was the Chief Executive Officer of KV from approximately 1975 until approximately December 5, 2008. As Chief Executive Officer, Hermelin was the highest ranking corporate executive in the company. Defendant Hermelin also owned or controlled the voting rights for significant amounts of KV’s publicly traded stock. Defendant was also a member of KV’s Board of Directors, serving as Vice Chairman of KV’s Board from 1975-2006, and Chairman of the Board from 2006-08. Defendant was also an officer of Ethex, a

corporate subsidiary of KV that branded and distributed generic drugs. By virtue of his role at KV and Ethex, defendant Hermelin had the power, authority, and responsibility to either prevent drug manufacturing problems in the first instance and the ability to promptly correct any violations of the Food, Drug, and Cosmetic Act that did occur at KV and Ethex.

4. While defendant Hermelin was the Chief Executive Officer of KV, KV pled guilty to misdemeanor charges involving the misbranding of drugs and the failure to file required reports with the Food and Drug Administration ("FDA") in 1995 in a case captioned United States v. KV Pharmaceutical Company, CR 95-0179, District of Maryland. KV was also the subject of three drug forfeiture lawsuits brought by the FDA, two of which were resolved in 1993 and one that was resolved in 2008. KV also received warning letters from FDA in 2000 about significant deviations from FDA's drug manufacturing regulations and in 2002 about drug marketing issues, and underwent FDA inspections with findings in 2003, 2004, 2006, 2007, 2008, and 2009. In 2009, KV and defendant executed a civil consent decree with FDA, placing the company's drug manufacturing activities under the supervision of FDA and the Court and subjecting defendant to its terms under certain circumstances in a case captioned: United States v. KV Pharmaceutical Co., ED-MO Case No. 4:09 CV 334 RWS.

THE DRUG MORPHINE SULFATE

5. At times relevant and material herein, morphine sulfate was an analgesic pain relief drug, controlled substance, and opiate. Morphine sulfate was a "drug" within the meaning of 21 U.S.C. § 321(g)(1) and was also a "prescription drug" within the meaning of 21 U.S.C. § 353(b)(1)(A) in that, due to the toxicity and other potentiality for harmful effect, and the method of use, the drug was not safe for use except under the supervision of a practitioner licensed by law to administer such drugs.

KV MANUFACTURED OVERSIZED DRUG TABLETS

6. During 2004, KV received seven complaints from consumers who received unusually large, thick, irregularly sized, and "lighter in color" tablets of oxycodone and hydromorphone that had been manufactured by KV. KV decided that no corrective action was warranted in response to the complaints, and did not recall these drugs or submit a field alert to the FDA.

7. During 2006-08, defendant Hermelin and KV's management team decided to increase both generic and branded tablet production of drugs on a daily and annual basis. To accomplish these goals, among other steps, KV decided to place several BB2 tablet press machines back into service to allow for the production of more total tablets to be manufactured per day and per year. Generally, BB2 tablet presses had less safety and automation features than the more modern tablet presses operated at KV. With more tablet press machines in service at KV, the amounts of drugs produced on a daily basis rose. Between 2006 and 2008, KV's drug production increased approximately 182%, from a daily average production of 4.1 million doses in 2006 to 10.6 million doses in April 2008.

8. On February 6, 2006, KV's internal manufacturing controls discovered several oversized morphine sulfate that had been pressed with BB2 machines before these tablets could be packaged and distributed into interstate commerce. On March 12, 2008, KV's internal manufacturing controls discovered several oversized plavetase tablets that had been pressed with BB2 machines before these tablets could be packaged and distributed into interstate commerce. Like the earlier 2004 complaints, KV's manufacturing processes were sporadically and occasionally creating oversized tablets during production runs of drug batches.

9. On May 7, 2008, KV received a complaint from a Walgreen's pharmacy in California. A pharmacist reported finding one oversized morphine tablet, 60 milligram ("mg") strength, in a 100 count bottle of tablets when filling a prescription for a customer. The oversized pill weighed over twice the specified amount, but had the same color and engraving as a normal and correctly sized tablet. This pill was manufactured by KV with a BB2 press in St. Louis County, Missouri.

10. On May 8, 2008, KV received a complaint from a Canadian distributor. A Canadian pharmacist reported finding one oversized morphine tablet, 30 mg strength, that was thicker than a "within specifications" sized 30 mg morphine tablet from the same tablet bottle. The oversized tablet had the same color and engraving as a normal correctly sized tablet. KV manufactured this tablet with a BB2 press in St. Louis County, Missouri. The Canadian distributor estimated that the oversized tablet weighed 65% more than a regular pill, and contained 60% more morphine than the 30 mg strength listed on the labeling for the drug.

11. Under the law, KV was required to thoroughly investigate any unexplained discrepancy in any of its drug products, or the failure of a drug batch to meet any of its specifications. Any such investigation under the law must extend to other batches of the same drug product and other drug products that may have been associated with the specific failure of discrepancy. Any drug company must make a written record of the investigation, including any conclusions and follow up. 21 C.F.R. § 211.192. When investigating these two morphine complaints, KV discovered that the "waste" from the production run for this batch of morphine tablets from the California complaint contained four additional oversized tablets.

12. On May 14, 2008, a KV pharmacist in KV's Medical & Clinical Affairs Department conducted a safety assessment, concluding that oversized morphine tablets in the 30 and 60 mg strength raised potential safety concerns for patients, including the possibility of acute overdosage, respiratory depression, stupor, coma, and even death.

13. On May 23, 2008, KV employees discovered two oversized morphine sulfate 30 mg tablets when sorting a batch of this drug product that had been pressed with a BB2 machine before these tablets had been packaged and distributed into interstate commerce.

14. On May 31, 2008, KV employees discovered four oversized buspirone tablets when sorting a batch of this drug product that had been pressed with a BB2 machine before these tablets were packaged and distributed into interstate commerce. This discovery occurred after KV had made some mechanical alterations to the BB2 machine that were designed to prevent additional oversized tablets from appearing.

15. On June 9, 2008, KV publicly announced a product recall for the single lot of morphine in the 60 mg format that included the oversize morphine tablet discovered by the Walgreen's pharmacist in California. The recall notice stated that wholesalers and retailers who may have received part of this single lot of 60 mg morphine had previously been contacted before June 9, 2008.

16. On June 13, 2008, KV issued a broader recall for specific additional lots of morphine, 30 mg and 60 mg strength. On June 18, 2008, KV also submitted a field alert to FDA referencing the discovery of oversized morphine tablets in the 30 mg and 60 mg strengths, but not disclosing the discovery of other oversized tablets of other types of drugs made with BB2 presses, such as plavetase and buspirone.

17. On June 19, 2008, KV employees discovered two oversized tablets of plaratese from two separate drug lots during gauge sorting after these lots had been manufactured with BB2 presses before these tablets had been distributed into interstate commerce. These oversized plaretase tablets appeared after KV had made some mechanical changes to the BB2 press that were designed to ensure that the BB2 press could not create oversized tablets.

18. While investigating the two morphine customer complaints that KV received during May 2008 pursuant to 21 C.F.R. § 211.192, KV employees concluded that the primary cause of oversized tablets was the use of BB2 machines. KV was unable to link the appearance of all identified oversized tablets to a specific employee operating a tablet press or the flow characteristics of the ingredients of a specific drug. Since KV used BB2 machines to make many other tablet drugs beyond morphine, KV's investigation therefore suggested that any lot of drug product made on BB2 machines in 2008 at KV were likely to include oversized tablets on a random and sporadic basis. KV explored a transition away from using BB2 machines to manufacturing all drugs with more modern and automated tablet press machines.

19. During June and July of 2008, defendant instructed KV employees to minimize written communications about KV's oversized tablet manufacturing problems and the company's investigation of these issues, and limit distribution and discussion of any documents discussing these problems given the "business risk" created by these written materials. Defendant wanted KV's Quality Assurance personnel to not be involved with the investigation of oversized tablets, stated that the Quality Assurance employees should be out of the "information flow," and suggested his views on what the root cause finding of the investigation should be.

MISBRANDING

20. The FDA is an agency of the United States government. Under the authority of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-394, FDA regulated the approval, manufacture, and distribution of drug products for human consumption.

21. Under the authority of the FDCA, 21 U.S.C. §§ 301-394, a drug was misbranded if the drug's labeling was false or misleading in any particular, or did not accurately state the contents of the drug in terms of weight or measure under the FDCA. 21 U.S.C. § 352(a), (b). Further, a drug was misbranded under the FDCA unless the labeling bore: (1) adequate directions for use, and; (2) such adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage as are necessary for the protection of users. 21 U.S.C. § 352(f).

COUNT ONE

22. The United States incorporates by reference paragraphs 1-21.

23. On or about April 16, 2008, in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, MARC S. HERMELIN, defendant herein, was a responsible corporate officer of KV under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a) and during that time KV introduced and caused the introduction and delivery into interstate commerce of a quantity of the drug morphine sulfate, 60 milligram strength, from St. Louis County, Missouri to San Francisco, California, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act in that the drug's labeling was false and misleading in that it stated that the drug was a uniform strength when a tablet of the drug was actually oversized and contained more of the active ingredient of the drug than the labeling's stated amount of 60 milligrams. All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a).

COUNT TWO

24. The United States incorporates by reference paragraphs 1-21 herein.


25. On or about December 19, 2007, in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, MARC S. HERMELIN, defendant herein, was a responsible corporate officer of KV under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a) and during that time KV introduced and caused the introduction and delivery into interstate commerce of a quantity of the drug morphine sulfate, 30 milligram strength, from St. Louis County, Missouri to Canada, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act because the drug's labeling was false and misleading in that it stated that the drug was a uniform strength when a tablet of the drug was actually oversized and contained more of the active ingredient of the drug than the labeling's stated amount of 30 milligrams. All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a).

UNITED STATES OF AMERICA)
EASTERN DIVISION)
EASTERN DISTRICT OF MISSOURI)

I, Andrew J. Lay, Assistant United States Attorney for the Eastern District of Missouri, being duly sworn, do say that the foregoing information is true as I verily believe.


Andrew J. Lay, #28542

Subscribed and sworn to before me this 10 day of February 2011.


CLERK, U.S. DISTRICT COURT

By: 
DEPUTY CLERK